UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

November 2018 Grand Jury

UNITED STATES OF AMERICA,

Plaintiff,

v.

BENEDICT LIAO,
aka "Wada Masao,"
aka "Masao A. Wada,"

Defendant.

Case No. SA CR 19- 00004 JVS

I N D I C T M E N T

[18 U.S.C. § 1343: Wire Fraud; 21 U.S.C. §§ 331(a), 333(a)(2), 352(a), (f)(1): Introducing Misbranded Drugs Into Interstate Commerce; 21 U.S.C. §§ 331(k), 333(a)(2), 352(a), (f)(1): Misbranding a Drug While Held for Sale After Shipment in Interstate Commerce; 21 U.S.C. §§ 331(d), 333(a)(2), 355(a): Introducing Unapproved Drugs Into Interstate Commerce; 18 U.S.C. § 2(b): Causing an Act to be Done]

The Grand Jury charges:

INTRODUCTORY ALLEGATIONS

At all times relevant to this Indictment:

A. THE DEFENDANT

1. Defendant BENEDICT LIAO, also known as ("aka") "Wada Masao," aka "Masao A. Wada" ("LIAO"), was a physician licensed in California who operated the Oeyama-Moto Cancer Research Foundation,

LLC and Oeyama-Moto Medical Group, LLC at offices located in Monterey Park, California and later in West Covina, California. Defendant LIAO manufactured the drug Allesgen at a location in Fullerton, California. Defendant LIAO was a naturalized U.S. citizen who was born in the Republic of China (Taiwan).

B. FEDERAL FOOD, DRUG, AND COSMETIC ACT

2. The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the American public by enforcing the Food, Drug, and Cosmetic Act ("FDCA"). One of the main purposes of the FDCA was to ensure that human drugs sold were safe, effective, and bear labeling containing only true and accurate information. The FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce.

3. The FDCA defined a "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," and "articles (other than food) intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(B) and (C).

4. A "prescription drug" was any drug which, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug"; or any drug which is "limited by an approved new drug application . . . to use under the professional supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1).

5. The FDCA further defined a "new drug" as any "drug" the composition of which is not generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs for use under the conditions prescribed, recommended or suggested in its labeling. 21 U.S.C. § 321(p).

6. Under the FDCA, a "new drug" could not be distributed unless FDA had approved a New Drug Application ("NDA") or an Abbreviated New Drug Application ("ANDA") with respect to the drug, or it qualified for an exemption allowing distribution for clinical testing as an Investigational New Drug ("IND"). 21 U.S.C. §§ 355(a), (i), 331(d). The manufacturer of the new drug was required to submit information in the NDA or ANDA showing to FDA's satisfaction that its new drug was safe and effective for its intended use. 21 U.S.C. §§ 355(b)(1), (j), (l); 21 C.F.R. § 314.50. Drugs that were the subject of an approved IND could not be distributed in interstate commerce unless and until the FDA approved an NDA or ANDA for such drugs. 21 U.S.C. §§ 355(a), 331(d); 21 C.F.R. §§ 314.7, 321.7(b). Investigational use pursuant to an IND application could not begin until 30 days after the FDA received the application. Furthermore, the investigation could not proceed, no distribution of the drug could be made, and any individuals who had received the drug must be taken off of it if FDA placed the drug on a "clinical hold." 21 U.S.C. § 355(i); 21 CFR Part 312.

7. Under the FDCA, "label" was defined as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). The term "labeling" was defined as "all labels and other written, printed, or graphic matter (1) upon

any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

8. The FDCA prohibited the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of any drug that was misbranded. 21 U.S.C. § 331(a).

9. Under the FDCA and FDA's regulations implementing that law, a drug was deemed to be "misbranded" if, among other things, its labeling was false or misleading in any particular, 21 U.S.C. § 352(a) or if its labeling failed to bear adequate directions for use, 21 U.S.C. § 352(f)(1). "Adequate directions for use" were directions under which a layperson could use a drug safely and for the purposes for which it was intended. 21 C.F.R. § 201.5. By definition, it was not possible to write "adequate directions for use" for a prescription drug because directions to a layperson cannot be adequate and professional supervision was required.

10. The FDCA defined a "dietary supplement" as "a product . . . intended to supplement the diet that bears or contains . . . a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet." 21 U.S.C. § 321(ff). Although general claims concerning the effect of a supplement's ingredient on the structure or function of the body were permitted, the FDCA prohibited any statement that a supplement can mitigate, treat, cure, or prevent a disease. 21 U.S.C. § 321(r)(6).

11. On December 3, 2011, under the alias "Masao A. Wada, M.D.," defendant LIAO submitted to FDA for review an IND application in which he stated that he planned to engage in a clinical trial of Allesgen. FDA received this IND application on December 15, 2011. On January 13, 2012, FDA informed defendant LIAO that this IND application for Allesgen had been placed on a full clinical hold. Under the alias "Masao Wada, M.D.," defendant LIAO submitted to FDA for review another IND for a clinical trial of Allesgen, which was dated October 3, 2012 and received by FDA on November 5, 2012. On December 5, 2012, FDA informed defendant LIAO that this IND for Allesgen had been placed on a full clinical hold. In the written notices that FDA sent to defendant LIAO regarding both of these clinical holds, defendant LIAO was told that he could not legally initiate or resume the proposed clinical trials of Allesgen.

COUNTS ONE THROUGH EIGHT

[18 U.S.C. § 1343]

12. The factual allegations set forth in paragraphs 1 through 11 are re-alleged and incorporated herein by reference.

A. THE SCHEME TO DEFRAUD

13. From in or about July 2012 through at least on or about January 16, 2018, in Orange and Los Angeles Counties, within the Central District of California, and elsewhere, defendant LIAO knowingly and with intent to defraud devised a scheme and artifice to defraud purchasers of the drug Allesgen and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, and the concealment of material facts, namely, by distributing and causing the distribution in interstate commerce of an unapproved new drug, Allesgen, when no NDA for Allesgen had been approved by the FDA; FDA had placed a hold on any distribution of Allesgen; and Allesgen's label was false, misleading, and did not bear adequate directions for use.

14. As part of the scheme and artifice to defraud, defendant LIAO did the following, among other things:

a. Although defendant LIAO knew that Allesgen required FDA approval before it could be lawfully distributed in interstate commerce based on, among other things, warnings that he received from FDA, defendant LIAO distributed and caused the distribution in interstate commerce of the drug Allesgen as a treatment for all types of cancer although the drug did not have the required FDA approval.

b. Defendant LIAO distributed Allesgen in interstate commerce after FDA placed defendant LIAO's IND application on a full clinical hold, which barred defendant LIAO from proceeding with any

clinical study and providing Allesgen to any human subject, and did not inform any individuals to whom he had provided Allesgen that it was on a clinical hold and that, as a result, those individuals should not continue to take Allesgen.

c. While promoting Allesgen as a cancer treatment, defendant LIAO did not disclose to his customers that he had not yet sought FDA approval for distribution of Allesgen in interstate commerce and that Allesgen was on a full clinical hold at the times listed below and therefore not even permitted to be used in a clinical trial. Instead, defendant LIAO distributed and caused Allesgen to be distributed in interstate commerce as an "effective" treatment for inhibiting and curing cancer that did not have side effects. Defendant LIAO also failed to make additional disclosures to his customers that were required by 21 U.S.C. § 355(i)(4) and that he told FDA he would include as part of his study. For example, he failed to tell customers that he was seeking permission from FDA to conduct an investigational study of Allesgen or describe the details of that study; that Allesgen had side effects that were unpredictable and could be very serious and long lasting and that there was a risk of death; that experimental medications were provided for free; that defendant LIAO would not charge recipients for Allesgen; and that Allesgen would only be given to stage III and IV cancer patients who had not been helped by radiation or chemotherapy and had no therapy available to them that provides clinical benefit.

d. FDA's regulations required that a drug distributed pursuant to an IND application bear a label stating that it was a "New Drug -- Limited by Federal . . . law to investigational use." 21 C.F.R. § 312.6(a). Defendant LIAO submitted to FDA a label that

he proposed to use for Allesgen, which stated in accordance with FDA's regulations, that Allesgen was an "investigational new drug" and that Allesgen was "limited by federal law to investigational use only." However, defendant LIAO did not use the proposed label. Defendant LIAO instead distributed Allesgen in interstate commerce bearing a label that misleadingly called Allesgen a "supplement," not a drug; said that the label "had not been evaluated by the FDA;" and failed to disclose any information about the investigational nature of Allesgen or any other information about its status with FDA or the potential side effects associated with Allesgen.

e. Defendant LIAO also falsely represented to FDA: that Masao Wada was a different person than defendant LIAO; that Masao Wada was a physician who was the sponsor of the Allesgen clinical investigation; that Masao Wada was the chairman of the Institutional Review Board, which was required for Allesgen as an investigational new drug; that Masao Wada was defendant LIAO's brother; and that Masao Wada was Japanese. In reality, "Masao Wada" was merely an alias for defendant LIAO himself, which defendant LIAO admitted in an interview with FDA employees.

f. During the time period of approximately July 2012 through June 26, 2014, defendant LIAO sold and distributed over 400 bottles of Allesgen at a price generally set at $2,000 per bottle, plus shipping, to customers in various states and in foreign countries, as a result of which he received at least approximately $814,948.95 in revenue. From approximately July 2014 through January 2018, defendant LIAO sold and distributed additional bottles of Allesgen to customers in various states and in foreign countries, as

a result of which he received additional revenue totaling approximately $800,000.

g. Defendant LIAO used interstate wires to conduct email communication with actual and potential Allesgen customers and to promote Allesgen through websites that defendant LIAO operated and that were accessed using interstate wires, and instructed customers to transmit funds for the purchase of Allesgen via interstate wire transfers to a bank account controlled by defendant LIAO.

B. USE OF INTERSTATE WIRES

15. On or about the dates set forth below, in Orange and Los Angeles Counties, within the Central District of California, for the purpose of executing and attempting to execute the above-described scheme and artifice to defraud, defendant LIAO knowingly and with intent to defraud caused to be transmitted by means of wire communications in interstate commerce, the writings, signs and signals described below:

COUNT	DATE	WIRE COMMUNICATION
ONE	11/15/2013	Wire transfer of $6,050 by T.C. in Florida to Oeyama Moto Medical Group's bank account #XXXXXXXX0548 at Bank of America in Monterey Park, California
TWO	11/20/2013	Wire transfer of $4,050 by D.T. in New York to Oeyama Moto Medical Group's bank account #XXXXXXXX0548 at Bank of America in Monterey Park, California
THREE	11/25/2013	Wire transfer of $12,050 by Q.M. in Alabama to Oeyama Moto Medical Group's bank account #XXXXXXXX0548 at Bank of America in Monterey Park, California
FOUR	12/10/2013	Wire transfer of $2,050 by B.H. in Washington to Oeyama Moto Medical Group's bank account #XXXXXXXX0548 at Bank of America in Monterey Park, California

COUNT	DATE	WIRE COMMUNICATION
FIVE	12/16/2013	Wire transfer of $4,050 by T.C. in Florida to Oeyama Moto Medical Group's bank account #XXXXXXXX0548 at Bank of America in Monterey Park, California
SIX	1/8/2014	Wire transfer of $2,050 by T.C. in Florida to Oeyama Moto Medical Group's bank account #XXXXXXXX0548 at Bank of America in Monterey Park, California
SEVEN	2/12/2014	Wire transfer of $10,050 by B.H. in Washington to Oeyama Moto Medical Group's bank account #XXXXXXXX0548 at Bank of America in Monterey Park, California
EIGHT	3/26/2014	Wire transfer of $2,050 by W.L. in Pennsylvania to Oeyama Moto Medical Group's bank account #XXXXXXXX0548 at Bank of America in Monterey Park, California

COUNTS NINE THROUGH SIXTEEN

[21 U.S.C. §§ 331(a), 333(a)(2), 352(a), (f)(1); 18 U.S.C. § 2(b)]

16. The factual allegations set forth in paragraphs 1 through 11, 13, and 14 are re-alleged and incorporated herein by reference.

17. On or about the following dates, in Orange and Los Angeles Counties, within the Central District of California, defendant LIAO, with intent to defraud and mislead customers and the FDA, introduced and willfully caused to be introduced a drug, namely, the following bottles of Allesgen, in interstate commerce to the following customers outside of California, when Allesgen was misbranded pursuant to Title 21, United States Code, Sections 352(a), (f)(1), in that Allesgen's labeling was false, misleading, and lacked adequate directions for use:

COUNT	DATE	NO. OF BOTTLES PURCHASED	AMOUNT PAID	BUYER	LOCATION
NINE	11/15/2013	3	$6,050	T.C.	Florida
TEN	11/20/2013	2	$4,050	D.T.	New York
ELEVEN	11/25/2013	6	$12,050	Q.M.	Alabama
TWELVE	12/10/2013	1	$2,050	B.H.	Washington
THIRTEEN	12/16/2013	2	$4,050	T.C.	Florida
FOURTEEN	1/8/2014	1	$2,050	T.C.	Florida
FIFTEEN	2/12/2014	5	$10,050	B.H.	Washington
SIXTEEN	3/26/2014	1	$2,050	W.L.	Pennsylvania

COUNTS SEVENTEEN THROUGH NINETEEN

[21 U.S.C. §§ 331(k), 333(a)(2), 352(a), (f)(1)]

18. The factual allegations set forth in paragraphs 1 through 11, 13, and 14 are re-alleged and incorporated herein by reference.

19. On or about the following dates, in Orange and Los Angeles Counties, within the Central District of California, defendant LIAO having received bromelain, a component of the drug Allesgen, in interstate commerce from Sigma Aldrich Labs in St. Louis, Missouri, with intent to defraud and mislead customers and the FDA, held the following bottles of Allesgen for sale, and caused those bottles of Allesgen to be misbranded in that Allesgen's labeling was false and misleading, and lacked adequate directions for use:

COUNT	DATE	NO. OF BOTTLES PURCHASED	AMOUNT PAID	BUYER	LOCATION
SEVENTEEN	12/27/2013	6	$12,050	M-C. T.	Fremont, CA
EIGHTEN	2/4/2014	2	$4,050	D.H.	Fremont, CA
NINETEEN	2/10/2014	10	$20,000	M-C. T.	Fremont, CA

COUNTS TWENTY THROUGH TWENTY-SEVEN

[21 U.S.C. §§ 331(d), 333(a)(2), 355(a); 18 U.S.C. § 2(b)]

20. The factual allegations set forth in paragraphs 1 through 11, 13, and 14 are re-alleged and incorporated herein by reference.

21. On or about the following dates, in Orange and Los Angeles Counties, within the Central District of California, defendant LIAO, with intent to defraud and mislead the FDA, introduced and willfully caused to be introduced a new drug, namely, the following bottles of Allesgen, in interstate commerce to the following customers outside of California, when Allesgen had not been approved through a new drug application filed pursuant to Title 21, United States Code, Sections 355(b), (i), or (j):

COUNT	DATE	NO. OF BOTTLES PURCHASED	AMOUNT PAID	BUYER	LOCATION
TWENTY	11/15/2013	3	$6,050	T.C.	Florida
TWENTY-ONE	11/20/2013	2	$4,050	D.T.	New York
TWENTY-TWO	11/25/2013	6	$12,050	Q.M.	Alabama
TWENTY-THREE	12/10/2013	1	$2,050	B.H.	Washington
TWENTY-FOUR	12/16/2013	2	$4,050	T.C.	Florida
TWENTY-FIVE	1/8/2014	1	$2,050	T.C.	Florida

COUNT	DATE	NO. OF BOTTLES PURCHASED	AMOUNT PAID	BUYER	LOCATION
TWENTY-SIX	2/12/2014	5	$10,050	B.H.	Washington
TWENTY-SEVEN	3/26/2014	1	$2,050	W.L.	Pennsylvania

A TRUE BILL

/S/

Foreperson

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